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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Derek O'Hagan

Serial No.: 09/724,661

Group Art Unit: Unassigned

Filing Date: November 28, 2000

Examiner: Unassigned

Title: USE OF HYALURONIC ACID POLYMERS FOR MUCOSAL  
DELIVERY OF VACCINE ANTIGENS

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. § 1.97

TRANSMITTAL LETTER

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is an Information Disclosure Statement, including a Form PTO-1449 and copies of the cited references. It is believed that no fee is due.

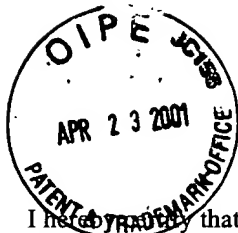
The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-1648.

Respectfully submitted,

Date: 19 April 2001

By: Gary R. Fabian  
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UNDER 37 C.F.R. § 1.97**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The information listed below may be material to the examination of the above-identified application. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is respectfully requested to make this information of official record in the application. The information includes:

U.S. Patent No. 3,891,570 issued June 24, 1975, to Fukushima et al.;

U.S. Patent No. 4,851,521 issued July 25, 1989, to della Valle et al.;

U.S. Patent No. 4,965,353 issued October 23, 1990, to della Valle et al.;

U.S. Patent No. 5,707,644 issued January 13, 1998, to Illum;

International Publication No. WO 95/17211 published June 29, 1995;

International Publication No. WO 96/29998 published October 3, 1996;

International Publication No. WO 97/07833, published March 6, 1997;

European Publication No. 0216 459 B1, published April 1, 1987;

European Publication No. 0433 133, published March 29, 1995;

- European Publication No. 0 517 565 A3, published December 9, 1992;
- Benedetti et al., "Microspheres of Hyaluronic Acid Esters-Fabrication Methods and *In Vitro* Hydrocortisone Release," *Journal of Controlled Release* 13:33-41 (1990);
- Cortivo et al., "*In Vitro* Studies on Biocompatibility of Hyaluronic Acid Esters," *Biomaterials* 12:727-730 (1991);
- Ghezze et al., "Hyaluronane Derivative Microspheres as NGF Delivery Devices: Preparation Methods and *In Vitro* Release Characterization," *International Journal of Pharmaceutics* 87:21-29 (1992);
- Illum et al., "Hyaluronic Acid Ester Microspheres as a Nasal Delivery System for Insulin," *Journal of Controlled Release* 29:133-141 (1994);
- Koichiro, "Vaccine for Rhinovaccination," Japanese Abstract Pub. No. 05163161 (1993);
- Kyyronen et al., "Methylprednisolone Esters of Hyaluronic Acid in Ophthalmic Drug Delivery: *In Vitro* and *In Vivo* Release Studies," *International Journal of Pharmaceutics* 80:161-169 (1992);
- Longenecker et al., "Effects of Sodium Taurodihydrofusidate on Nasal Absorption of Insulin in Sheep," *Journal of Pharmaceutical Sciences* 76(5):351-355 (1987);
- O'Hagan et al., "The Preparation and Characterization of Poly(lactide-co-glycoside) Microparticles: III Microparticle/Polymer Degradation Rates and the *In Vitro* Release of a Model Protein," *International Journal of Pharmaceutics* 103:37-45 (1994);
- Pritchard et al., "Evaluation of the Bioadhesive Properties of Hyaluronan Derivatives: Detachment Weight and Mucociliary Transport Rate Studies," *International Journal of Pharmaceutics* 129:137-145 (1996);
- Richardson et al., "Novel Vaginal Delivery Systems for Calcitonin: I. Evaluation of HYAFF/Calcitonin Microspheres in Rats," *International Journal of Pharmaceutics* 115:9-15 (1995);

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Richardson et al., "Gamma-Scintigraphy as a Novel Method to Study the Distribution and Retention of Bioadhesive Vaginal Delivery System in Sheep," *Journal of Controlled Release* 42:133-142 (1996); and

Sharif and O'Hagan, "A Comparison of Alternative Methods for the Determination of the Levels of Proteins Entrapped in Poly(Lactide-Co-Glycoside) Microparticles," *International Journal of Pharmaceutics* 115:259-263 (1995).

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

Date: 19 April 2001

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